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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/050,664 | 01/16/2002 | Dan E. Fischer | 7678.567 | 6069 |
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| WORKMAN NYDEGGER (F/K/A WORKMAN NYDEGGER & SEELEY) 60 EAST SOUTH TEMPLE 1000 EAGLE GATE TOWER SALT LAKE CITY, UT 84111 | | | EXAMINER CHIN, BRAD Y | |
| | | | ART UNIT 1744 | PAPER NUMBER |
| DATE MAILED: 08/16/2005 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/050,664 | FISCHER ET AL. |
| | Examiner | Art Unit |
| | Brad Y. Chin | 1744 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 June 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 25,27 and 28 is/are allowed.
- 6) Claim(s) 1-24 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Objections

1. Claim 12 is objected to because of the following informalities: Applicants provide proper antecedent basis for the "an endodontic file" in claim 1. Thus, the claim language should be amended to the following: "A method as defined in claim 11, wherein the endodontic tool comprises the endodontic file". Appropriate correction is required.

Specification

2. The disclosure is objected to because of the following informalities: Applicants recite an endodontic file in claims 1 and 12, but fail to provide description of such structural limitation in the specification. Applicants do .

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-4 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn [U.S. Patent No. 6,139,320] in view of Nance [U.S. Patent No. 6,638,064].

Regarding claim 1, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising: providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Figure 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and introducing a viscous disinfecting composition into the root canal in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal, wherein the viscous disinfecting composition is able to adhere to walls of the root canal so as to enable the disinfecting composition to disinfect the root canal (See col. 7, line 66 to col. 8, line 43 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – “slurry”; and a gelling agent – gels of glycerine or gelatine, into the root canal, where the addition of aerosiles changes the viscosity of the gels, providing for the ability of the disinfecting composition to overcome gravity, making it possible to renounce continuous supplies of the disinfecting composition, i.e. allowing the viscous disinfecting composition to adhere to the walls of the root canal so as to enable the disinfecting composition to disinfect the root canal area; See col. 4, lines 1-9 – Hahn teaches the use of an

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oscillating/vibrating device for preparing human and animal hard or soft tissue and of dental or bone replacement materials, which has a considerable shorter length than prior art ultrasonic treatment instruments and can be handled in an ergonomically favorable way like a prior art angled hand piece, thus allowing for economic use of such a tool in regions, which are difficult to access, e.g. in the intraoral treatment of hard tissue – Hahn's endodontic tool provides the user with control in performing dental procedures, similar to other dental instruments commonly used by dentists and oral surgeons).

Hahn fails to teach that the viscous disinfecting composition is introduced into the root canal using an endodontic file. Nance teaches a method for irrigating a root canal and an endodontic apparatus for use in performing root canal therapy on a tooth, which is particularly useful for irrigating a root canal possessing a non-linear central axis. Nance teaches that endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite (See col. 1, lines 27-35). Accordingly, Nance teaches a flexible endodontic tool, which comprises an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application) and where the viscous disinfecting composition is introduced into the root canal by means of the endodontic file (See Figure 1; See col. 3, line 48 to col. 4, line 8 – the shank comprises an enclosed axial channel or lumen 16 extending the length of the shank for delivering fluid for irrigating of disinfecting the root canal of

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a tooth). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the endodontic file with means for delivering a fluid from the distal end of the endodontic file, as taught by Nance, with the endodontic tool and viscous disinfecting composition, as taught by Hahn, because Hahn teaches an apparatus and method for disinfecting a root canal during an endodontic procedure, where the endodontic tool of Hahn provides a controlled manner for introduction of a viscous disinfecting composition through the lumen of the endodontic file of Nance, and out the distal end of the endodontic file for delivering the viscous disinfecting composition to the root canal of a tooth.

Regarding claim 2, Hahn teaches the method as defined in claim 1, wherein the viscous disinfecting composition comprises sodium hypochlorite, water, and a gelling agent (See col. 8, lines 9-43 – viscous disinfecting composition comprises sodium hypochlorite, water, e.g. for the slurry, and a gelling agent, e.g. glycerine or gelatine or 1 to 10% chloro-hexidine-digluconate-gel).

Regarding claim 3, Hahn teaches the method as defined in claim 2, wherein the gelling agent comprises at least one finely divided particulate gelling agent (See col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles, making the gel more viscous and providing for the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

Regarding claim 4, Hahn teaches the method as defined in claim 3, wherein the finely divided particulate gelling agent comprises at least one of fumed silica or fumed aluminum oxide (See col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles – a

suitable fumed silica gelling agent, making the gel more viscous and allowing the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

Regarding claims 11 and 12, Nance teaches a method for irrigating a root canal and an endodontic apparatus for use in performing root canal therapy on a tooth, which is particularly useful for irrigating a root canal possessing a non-linear central axis. Nance teaches that endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite (See col. 1, lines 27-35). Accordingly, Nance teaches a flexible endodontic tool, which comprises an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application) and where the viscous disinfecting composition is introduced into the root canal by means of the endodontic file (See Figure 1; See col. 3, line 48 to col. 4, line 8 – the shank comprises an enclosed axial channel or lumen 16 extending the length of the shank for delivering fluid for irrigating of disinfecting the root canal of a tooth). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nance with Hahn's method because Hahn teaches an apparatus and method for disinfecting a root canal during an endodontic procedure, where such combination produces an endodontic tool, comprising numerous tools attached to the endodontic tool, such as tools providing the capability for cleaning at least a part of the root canal with the endodontic tool and subsequently irrigating the root canal to remove the viscous

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disinfecting composition and any loosened pulp or other debris after a predetermined period of time.

Regarding claim 13, Hahn in view of Nance teach the method for disinfecting a root canal during an endodontic procedure as described above, but fail to teach the method where the viscous disinfecting composition is left in the root canal for a time in a range of about 1 minute to about 1 hour. It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the appropriate amount of time that the viscous disinfecting composition of Hahn in view of Nance should be left in the root canal during such an endodontic procedure. Use of sodium hypochlorite is a common disinfectant in endodontic procedures and thus one of ordinary skill in the art, without undue experimentation, would be able to determine that leaving the viscous disinfecting composition of Hahn in view of Nance in the root canal for a time ranging from about 1 minute to about 1 hour would be appropriate to disinfect the bacteria in the root canal.

4. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Nance, as described above in paragraph 3, and further in view of Clay [U.S. Patent No. 6,413,499].

Hahn in view of Nance teach the method for disinfecting a root canal during an endodontic procedure as defined above in paragraph 3, but fail to teach the method, where the gelling agent comprises at least one polymeric gelling agent or where the gelling agent comprises carboxypolymethylene.

Regarding claim 5, Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed

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with water, where the gelling agent comprises at least one polymeric gelling agent, e.g. polyalkylene glycol, polypropylene glycol, etc. (See col. 9, lines 52 to col. 10, line 5).

Regarding claim 6, Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises carboxypolymethylene (See col. 9, lines 52 to col. 10, line 5). Clay further teaches "whereas the liquid carrier is superior in terms of the rate and extent of penetration and absorption of the active agents, the gel carrier is superior in terms of tissue adhesion and the ability to remain where initially placed (See col. 10, lines 7-11). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Clay with Hahn in view of Nance because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. adhere to the walls of the root canal, making it possible to renounce a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, carboxypolymethylene, would serve as a thickener for the disinfecting composition.

5. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Nance, as described above in paragraph 3, and further in view of Lee et. al. [U.S. Patent Publication No. 2002/0192627].

Regarding claim 7-10, Hahn in view of Nance teach the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 3, but fails to teach the method where the sodium hypochlorite is included in a range of about 0.01% to about 50%

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[claim 7]; about 0.1% to about 40% [claim 8]; about 1% to about 20% [claim 9]; and about 1% to about 20% [claim 10] by weight of the viscous disinfecting composition.

Lee et. al. teach a dental training device where the viscous disinfecting composition comprises sodium hypochlorite and other constituents in the range from about 1 to 80% by weight (See col. 6, [0057]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lee et. al. with Hahn in view of Nance because it would have been obvious to formulate a viscous disinfecting composition comprising sodium hypochlorite in the ranges defined in claims 7-10 with other constituents, without undue experimentation, to provide a suitable disinfectant concentration for disinfecting and sanitizing the root canal during such an endodontic procedure.

6. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Nance, as described above in paragraph 3, and further in view of Dickson et. al. [U.S. Patent No. 5,593,458].

Hahn in view of Nance teach the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 3, but fail to teach the method where the viscous disinfecting composition has a viscosity in a range from about 500 cps to about 20,000 cps [claim 14]; about 5,000 cps to about 100,000 cps [claim 15]; and 10,000 cps to about 50,000 cps [claim 16]. Dickson teaches that a gel may be made in a variety of ways, but the gel used will typically substantially cling to a vertical surface and has a preferred viscosity range. Dickson teaches that by varying the amount of gelling or thickening agent, the viscosity resulting from the mixture in this particular invention would preferably be between 6,500 and 50,000 cps as measured in a 600 ml beaker using a Brookfield Model RD Viscometer (See Specification, col. 3, lines 24-32).

Because it is well known in the art and supported in Dickson that a gelling agent allows a user to alter the viscosity of an aqueous composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dickson with Hahn for adding a gelling agent into a viscous disinfecting composition to produce a desired viscosity in the ranges defined in claims 14-16, without undue experimentation, providing a suitable viscous disinfectant composition that adheres to the walls of a root canal during such an endodontic procedure.

7. Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Nance, as applied above in paragraph 3, and further in view of Argo et. al. [U.S. Patent No. 5,731,276].

Regarding claims 17-19, Hahn in view of Nance fail to teach the method where the viscous disinfecting composition has a pH in a range from about 8 to about 12.5 [claim 17]; from about 10 to about 12 [claim 18]; and from about 11 to about 11.5 [claim 19]. Argo et. al. teach the use of an electrolyte/buffer base, which provides thickening, may act to maintain pH, which is favored for purposes of both achieving desirable rheology and maintaining halogen bleach stability, where a source of bleach is selected from various halogen bleaches, e.g. sodium hypochlorite. Argo et. al. further teaches the use of the electrolyte/buffer base functioning to keep the pH of the composition preferably above 7.0, more preferably at between 10.0 to about 14.0 (See col. 7, line 66 to col. 8, line 63). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Argo et. al. with the method and disinfecting composition comprising the mixture products of the bleaching compound – sodium hypochlorite, water, a gelling agent, and a base for use in formulating a viscous disinfecting composition for use in the method, as taught by Hahn in view of Nance,

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because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. to adhere to the walls of the root canal, making it possible to renounce a continuous supply a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent serves as a thickener for the disinfecting composition, where the electrolyte/buffer base, as taught by Argo et. al., functions to maintain the level of pH in the composition for increasing the stability of the bleaching compound while not substantially destroying the gel stability of the gelling agent.

8. Claims 20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Clay and Argo et. al.

Regarding claim 20, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising: providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Figure 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and introducing a viscous disinfecting composition into the root canal, the disinfecting composition comprising the mixture products of: sodium hypochlorite, water, and a gelling agent, included in an amount in order for the disinfecting composition to have a viscosity sufficient to remain in place within the root canal and disinfect accessory canals prior to rinsing (See col. 7, line 66 to col. 8, line 43 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – “slurry”; and a gelling agent – gels of glycerine or gelatine, into the root canal, where the addition of aerosiles changes the viscosity of the gels,

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providing for the ability of the disinfecting composition to overcome gravity, making it possible to renounce continuous supplies of the disinfecting composition, i.e. allowing the viscous disinfecting composition to adhere to the walls of the root canal so as to enable the disinfecting composition to disinfect the root canal area).

Hahn fails to teach that the gelling agent comprises at least one member selected from the group consisting of fumed silica, fumed aluminum oxide, and carboxypolymethylene and that the disinfecting composition includes a base in an amount so as to raise the pH of the disinfecting composition in order to increase the stability of the sodium hypochlorite while not substantially destroying gel stability of the gelling agent. Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises carboxypolymethylene (See col. 9, lines 52 to col. 10, line 5). Clay further teaches "whereas the liquid carrier is superior in terms of the rate and extent of penetration and absorption of the active agents, the gel carrier is superior in terms of tissue adhesion and the ability to remain where initially placed (See col. 10, lines 7-11). Argo et. al. teach the use of an electrolyte/buffer base, which provides thickening, may act to maintain pH, which is favored for purposes of both achieving desirable rheology and maintaining halogen bleach stability, where a source of bleach is selected from various halogen bleaches, e.g. sodium hypochlorite. Argo et. al. further teaches the use of the electrolyte/buffer base functioning to keep the pH of the composition preferably above 7.0, more preferably at between 10.0 to about 14.0 (See col. 7, line 66 to col. 8, line 63). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Clay and Argo et. al. with the method and disinfecting composition comprising the mixture products of the bleaching compound – sodium hypochlorite, water, a gelling agent, and a base for use in formulating a viscous disinfecting composition for

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use in the method, as taught by Hahn, because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. to adhere to the walls of the root canal, making it possible to renounce a continuous supply a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, carboxypolymethylene, would serve as a thickener for the disinfecting composition, where the electrolyte/buffer base, as taught by Argo et. al., functions to further to increase the stability of the bleaching compound, as taught by Argo et. al., while not substantially destroying the gel stability of the gelling agent.

Regarding claims 22 and 23, Argo et. al. teach the method using the electrolyte/buffer to keep the pH of the bleaching composition in a range from 10 to about 12 [claim 22]; and from about 11 to about 11.5 [claim 23]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Argo et. al. with Clay and Hahn for raising the pH of the viscous disinfecting composition at an effective pH level for maintaining the stability of the gelling agent within the viscous disinfecting composition.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Clay and Argo et. al., as applied above in paragraph 6, and further in view of Giletto et. al. [U.S. Patent No. 6,569,353].

Hahn in view of Clay and Argo et. al. teach the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 6, but fail to teach the gelling agent comprises fumed silica.

Giletto et. al. teach the use of fumed silica as an ideal gelling agent, performing two primary functions of reinforcement and rheology (flow) control. Reinforcement increases the

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strength or viscosity of various materials. The viscosity of the gel can be easily tailored to suit a specific situation (See col. 7, lines 10-28). Giletto et. al. further explain that fumed silica is widely available and is generally used in small quantities in many products such as toothpaste, detergents, food, coatings, adhesives, concrete, cosmetics, inks, plastics, and various types of rubbers. Fumed silica acts to thicken, and suspend solids. Fumed silica gel provides good surface coverage because of its free flowing character and holds the reactive components of the formulation in-place for extended periods. Sorption of the contaminant into the gel matrix is highly effective because of the enormous surface area the fumed silica provides and because of the relatively large volume available for dissolution (See col. 7, lines 29-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Giletto et. al. with Hahn in view of Clay and Argo et. al. because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. adhere to the walls of the root canal, making it possible to renounce a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, fumed silica, function as a thickener for the disinfecting composition.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Clay and Argo et. al., as applied above in paragraph 6, and further in view of Nance.

Hahn in view of Clay and Argo et. al. teach the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 6, but fail to teach the method further comprising cleaning at least a part of the root canal with an endodontic tool; and

irrigating the root canal to remove the viscous disinfecting composition and any loosened pulp or other debris.

Nance teaches a method for irrigating a root canal and an endodontic apparatus for use in performing root canal therapy on a tooth, which is particularly useful for irrigating a root canal possessing a non-linear central axis. Nance teaches that endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite (See col. 1, lines 27-35). Accordingly, Nance teaches a flexible endodontic tool, which comprises an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application) and where the viscous disinfecting composition is introduced into the root canal by means of the endodontic file (See Figure 1; See col. 3, line 48 to col. 4, line 8 – the shank comprises an enclosed axial channel or lumen 16 extending the length of the shank for delivering fluid for irrigating of disinfecting the root canal of a tooth). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nance with Hahn in view of Clay and Argo et. al.'s method because Hahn teaches an apparatus and method for disinfecting a root canal during an endodontic procedure, where such combination produces an endodontic tool, comprising numerous tools attached to the endodontic tool, such as tools providing the capability for cleaning at least a part of the root canal with the endodontic tool and subsequently irrigating the root canal to remove the viscous

disinfecting composition and any loosened pulp or other debris after a predetermined period of time.

Response to Arguments

11. Applicants' arguments, see pages 7-8, filed 13 June 2005, with respect to the rejection(s) of claim 1 under 35 U.S.C. 102(b) as being anticipated by Hahn [U.S. Patent No. 6,139,320] and with mention of Nance [U.S. Patent No. 6,638,064], as applied to claim 12, have been fully considered. Examiner agrees that, independently, Hahn fails to teach the use of an endodontic file to introduce a viscous disinfecting composition into a root canal. In view of the recited claim language, Examiner disagrees that the method of claim 1 provides a more controlled application of the disinfecting composition compared to the oscillating device of Hahn. Hahn provides an endodontic tool, like many tools commonly used by dentists and oral surgeons in performing routine dental procedures in a controlled manner, and a method for the tool's use, which is designed to allow the user to provide access to a root canal of a tooth and to introduce a viscous disinfecting composition into the root canal in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal. In view of Applicants' amended claim language, the rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Hahn has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Nance, as described above in paragraph 3.

Nance provides an endodontic tool comprising an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application). Examiner agrees that Nance is "particularly useful in irrigating a root canal"; however, Nance also provides the structural limitations and functionality

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of an endodontic file allowing for the delivery of fluid from a distal end of the shank, where in combination with the teachings of Hahn, one of ordinary skill in the art could have used the endodontic tool, as taught by Hahn, comprising the endodontic file, as taught by Nance, for delivering a viscous disinfecting composition, as taught by Hahn, from the distal end of the endodontic file into the root canal of a tooth.

12. Applicants' arguments, see pages 9-10, filed 13 June 2005, with respect to the rejection(s) of claim 20 have been fully considered. Examiner agrees that the cited references do not teach the amended claim language as recited, which includes the limitation for a base in an amount so as to raise the pH of the disinfecting composition in order to increase the stability of the sodium hypochlorite while not substantially destroying gel stability of the gelling agent; however, upon further consideration, a new ground(s) of rejection is made in view of Argo et. al. [U.S. Patent No. 5,731,276], as described above in paragraph 6.

13. Applicant's arguments, see page 10, filed 13 June 2005, with respect to claim 25 has been fully considered and are persuasive. The rejection of claim 25 has been withdrawn.

Allowable Subject Matter

14. Claims 25 and 27-28 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: Claims 25 and 27-28 include the limitations for introducing a viscous disinfecting composition into a root canal, the disinfecting composition comprising the mixture products of sodium hypochlorite in an amount of about 1% to about 20% by weight, water, at least one of fumed silica or fumed aluminum oxide in an amount in a range of about 1% to about 10% by weight,

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and a base included in amount so that the pH of the composition is in a range of about 10 to about 12. Hahn [U.S. Patent No. 6,139,320], Argo et. al. [U.S. Patent No. 5,731,276], and Giletto et. al. [U.S. Patent No. 6,569,353] teach the method for providing access to a root canal of a tooth; and introducing a viscous disinfecting composition into a root canal, the disinfecting composition comprising the mixture products of sodium hypochlorite, water, at least one of fumed silica or fumed aluminum oxide in an amount in a range of about 1% to about 10% by weight, and a base included in amount so that the pH of the composition is in a range of about 10 to about 12, but fail to teach that the sodium hypochlorite is in an amount in a range of about 1% to about 20% by weight in a mixture with the other constituents and a base included in an am amount so that the pH of the composition is in a range of about 10 to about 12. None of the references teach all the claimed limitations nor would it have been obvious to combine references to achieve the claimed inventive subject matter, more particularly the specific percentages claimed for the sodium hypochlorite and the fumed silica or fumed aluminum oxide in a mixture product with the other constituents.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sun (John) Kim, can be reached at 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc
August 10, 2005


JOHN KIM
SUPERVISORY PATENT EXAMINER